UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA *et al.* *ex rel.* JULIE LONG, Plaintiffs, v. JANSSEN BIOTECH, INC., Defendant.	)	Civil Action No. 16-CV-12182-FDS

RELATOR'S SUR-REPLY MEMORANDUM OF LAW
IN FURTHER OPPOSITION TO
DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS

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For the reasons stated in Relator's opening brief as well as the reasons set forth herein, Janssen's motion requesting that the Court grant it immunity from Relator's Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") claims and dismiss this action under the FCA's public disclosure provision, 31 U.S.C. § 3730(e)(4), should be denied.

Three years into this litigation and shortly after the Court ordered it to provide substantial discovery that it had delayed and evaded producing for over a year, Janssen asserted for the first time that it believes the FCA's public disclosure bar applies because a few snippets of vague information, assertions, and allegations from three lawsuits filed back in 2001, 2002, and 2007 would have put the Government on notice of the fraud Relator alleges. Janssen's asserted public disclosure theory is meritless, as it meets none of the FCA's requirements for a public disclosure. The purported disclosures did not allege the essential elements of the fraud Relator alleges, much less reveal that Janssen's predecessor was engaging in the same conduct. The purported disclosures also cannot qualify as public disclosures under the FCA because they were not made in lawsuits in which "the Government or its agent is a party," as the statute explicitly requires.

Moreover, even if the public disclosure theory Janssen has constructed could have somehow put the Government on notice of the fraud Relator alleges, Janssen's motion still fails. Relator, who directly participated in the alleged kickback scheme for 13 years, has made numerous material, and indeed essential, additions to any possible public disclosures. Her knowledge and information are entirely independent of the outdated and, in many cases, irrelevant purported disclosures Janssen has unearthed and strung together. And she satisfied all the FCA's pre-filing requirements. Relator indisputably satisfies the original source exception to the public disclosure bar. She is not an opportunist, and her allegations are plainly not parasitic. Congress amended the public disclosure provision to protect this very type of action.

I. THE PUBLIC DISCLOSURE BAR DOES NOT APPLY

The public disclosure bar is triggered only if three requirements are met: "(1) a public disclosure of the allegations or transactions in a relator's complaint ... occurred; (2) said disclosure ... occurred in the manner which is specified in the FCA; and (3) the relator's suit is 'based upon' those publicly disclosed allegations or transactions." *U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc*., Civ. No.21-11627, 2022 WL 17417577, at *8 (D. Mass. Dec. 5, 2022) (Saylor, C.J.) (quoting *U.S. ex rel. Est. of Cunningham v. Millennium Lab'ys of Cal., Inc.*, 713 F.3d 662, 669-70 (1st Cir. 2013)). The public disclosure theory Janssen asserts satisfies none of these statutory requirements.

A. The Alleged Public Disclosures Were Not Made In A Federal Civil Hearing In Which The Government Or Its Agent Was A Party

Janssen bases its public disclosure argument on outdated information, assertions, and allegations from three old lawsuits: (i) *In re Pharmaceutical Industry Average Wholesale Price ("AWP") Litigation,* No.01-12257-PBS (D. Mass.) (the "*AWP Class Action*") (filed in 2001); (ii) *U.S. ex rel. Heineman v. Johnson & Johnson, et al.*, No.02-cv-40469 (S.D. Iowa) (filed in 2002); and (iii) *U.S. ex rel. Greer v. Johnson & Johnson d/b/a Centocor*, No.07-sc-1660 (D. Minn.) (filed in 2007). However, because the Government was not a party to any of these actions, and none of the parties were agents of the Government, the information, assertions, and allegations Janssen has assembled from the lawsuits cannot trigger the FCA's public disclosure bar.

1. The Government was not a party to the *AWP Class Action*

As part of its 2010 amendment of the public disclosure provision, Congress narrowed the provision's first disclosure category, 31 U.S.C. § 3730(e)(4)(A)(i), by limiting it to allegations disclosed "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party." This statutory requirement is unambiguous.

Janssen does not contend that any of the parties to the *AWP Class Action* were agents of the Government, and it concedes that the United States was not a plaintiff or defendant to the action. Instead, it asserts that "party" should be interpreted broadly such that the United States is treated as a "party" to the *AWP Class Action* for purposes of the public disclosure provision. This argument disregards that Congress specifically added the language "in which the Government or its agent is a party" to narrow which lawsuits can be the source of allegations that may trigger the public disclosure bar. Janssen cannot cite any decision in which a court has determined that it has the authority to interpret "party," as used in § 3730(e)(4)(A)(i), to include any status other than a plaintiff or defendant. The requirement is unambiguous and cannot be disregarded.

In its reply, Janssen repeats the baseless argument that the Government should be treated as a party to the *AWP Class Action* merely because it was noted on the docket as an "interested party," it received copies of filings, and submitted briefing. This did not make the Government a party. In a non-intervened qui tam, the Government is the real party in interest, it receives copies of all filings, and it submits filings, including oftentimes briefing. Yet, it is settled law that the Government is not a party to a non-intervened qui tam. *See U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933 (2009). Janssen's contention that the Court should reach the opposite conclusion here should be rejected.

Because the Government was not a party to the *AWP Class Action*, Janssen resorts to asserting that the Court should nevertheless treat the snippets of information and allegations from the *AWP Class Action* as public disclosures because, in *U.S. ex rel. Lager v. CSL Behring, LLC*, 158 F. Supp.3d 782 (E.D. Mo. 2016), the court deemed information reported in the court's findings from the trial in the *AWP Class Action* to be public disclosures. *See* 158 F. Supp.3d at 790 (citing *In re Pharm. Indus. AWP Litig.*, 491 F.Supp.2d 20, 31 (D. Mass. 2007)). However,

the relator in *Lager* did not argue, and therefore the court did not take into account, that such information cannot constitute a public disclosure because the Government was not a party to the *AWP Class Action* (perhaps because it would have been futile to do so, as his allegations had been publicized in numerous earlier OIG reports, Congressional hearings, and in the news media, as the court in *Lager* detailed). In any event, to the extent that the courts in *Lager* considered information from the *AWP Class Action* to be public disclosures, they did so erroneously.

Inasmuch as the Government was not a party to the *AWP Class Action* and the actual parties to that action were not agents of the Government, none of the information and allegations from that lawsuit can constitute public disclosures under the FCA's public disclosure bar.

2. The relators in *Heineman* and *Greer* were not agents of the Government

Because the Government declined to intervene in the *Heineman* and *Greer* qui tam actions, it likewise was not a party to those cases. *See Eisenstein*, 556 U.S. at 933. The few courts that have considered whether a relator in a non-intervened qui tam is an agent of the Government have reached different conclusions. As Relator explains in her opening brief, the holding in *U.S. ex rel. Forney v. Medtronic, Inc.*, 327 F. Supp.3d 831 (E.D. Pa. 2018), that a relator is not an agent of the Government is the correct view on this issue. As the *Forney* court reasoned, an agency relationship does not exist because a relator in a non-intervened qui tam is not the Government's representative, and the Government cannot tell the relator what to do or how to litigate the action. *See* 327 F. Supp.3d at 843-44. Janssen exaggerates that "courts across the country" have held that a relator is an agent of the Government. It can cite just three decisions, two from the same circuit. Relator submits that the factors those courts relied upon—*i.e.*, the Government's status as the real party in interest, receipt of pleadings, need to approve of a dismissal or settlement, right to intervene at a later date, and ability to seek dismissal (*see, e.g.,*

U.S. ex rel. Holloway v. Heartland Hospice, Inc., 960 F.3d 836, 845 (6th Cir. 2020))—do not create an agency relationship between a relator and the Government. This is particularly true in cases where, as occurred in both *Heineman* and *Greer*, the relator takes no further steps to pursue the claims after the Government opts not to intervene.

Since the Government was not a party to *Heineman* and *Greer*, and the relators were not agents of the Government, the purported disclosures from these actions cannot constitute public disclosures under the FCA's public disclosure provision.

B. The Fraud Relator Alleges Was Not Previously "Publicly Disclosed"

The snippets of outdated information, allegations, and assertions from the *AWP Class Action* and vague allegations from the *Heineman* and *Greer* complaints that Janssen has misleadingly pieced together constitute "public disclosures" only if they provided sufficient information concerning the essential elements of the fraud that Relator alleges such that the Government should have already been on notice of the fraud. *See U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 208-209 (1st Cir. 2016); *U.S. ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 54 (1st Cir. 2009)). Likewise, as this Court directed, "[t]o be a disclosure of fraud the disclosure must contain either (1) a direct allegation of fraud, or (2) both a misrepresented state of facts and a true state of facts so that the listener or reader may infer fraud." *Flanagan*, 2022 WL 17417577, at *9 (quoting *U.S. ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 110 (1st Cir. 2010)).

Janssen manufactured its public disclosure theory by taking bits and pieces of information and assertions that it dug out of the mountain of filings in the *AWP Class Action* and stringing them together with a few vague allegations from the *Heineman* and *Greer* complaints. In its reply, Janssen continues embellishing the information, assertions, and allegations and

distorting their meaning through out-of-context quotes and paraphrasing. When the purported disclosures are read in context and compared to Relator's allegations, it is clear that they would not have put the Government on notice of the fraud that Relator alleges. By way of example, contrary to Janssen's assertions, Hoffman did not testify in the *AWP Class Action* that Centocor provided the practice management program to select physician practices ***on an ongoing basis***, as Relator alleges. Rather, Hoffman merely testified that the program provided information to help doctors provide "infusions in a more effective and efficient manner on an ongoing basis." Relator's Ex. 2 - Alleged Disclosure B-1. Furthermore, there was no testimony in this alleged disclosure specifying (i) what the "programs" were; (ii) who provided them; (iii) how they were provided; (iv) when they were provided; (v) that they had substantial independent value beyond Remicade; (vi) that they were provided for free; (vii) that they caused false claims to be submitted; or (viii) that Centocor knew they violated the law. Moreover, when considered in connection with the Court's June 2007 findings from the *AWP Class Action* trial, the "practice management program" discussed appears to have been focused on "buying, infusing, and billing for Remicade" and the profit that could be earned on Remicade, which was provided as part of Centocor's marketing the spread practice. *See* Relator's Ex. 2 - Alleged Disclosure L. Similarly, Janssen continues to exaggerate the significance of the Office Based Infusion Guide (Def.'s Ex. I) and the Remicade Practice Management Assistant (Def.'s Ex. H). These documents did not report that Centocor was having a special internal team of practice management consultants and outside consultants provide business advisory services that had substantial independent value beyond Remicade to select customers free of charge, as Relator alleges. It must be underscored again that Janssen did not even consider the Remicade Practice Management Assistant (Def.'s Ex. H) and the 1998 "cA2 marketing plan" (Def.'s Ex. K) to be important or relevant enough to

raise them in its March 2020 motion to dismiss or to even produce them to Relator in discovery.

Janssen also makes straw man arguments to try to create the appearance of a public disclosure, such as arguing that the earlier cases disclosed that Centocor provided doctors information about billing and coding for Remicade, obtaining insurance coverage for a Remicade infusion, and the logistics of performing a Remicade infusion, even though Relator does not assert a claim based on these services. Nor does Relator allege that merely making available or providing a written guide regarding setting up an infusion suite constitutes illegal remuneration. In addition, contrary to Janssen's public disclosure theory, Relator asserts no allegation concerning cash payments to help doctors open in-office infusion suites.

Much differently, Relator's allegations concern Janssen's strategy and practice of having its special team of practice advisors, called Area Business Specialists ("ABSs"), and outside consultants, such as Xcenda, advise doctors who were interested in opening an in-office infusion suite ("IOI") on how to open the IOI and also assisted them with getting it up and running. Additionally, Janssen had the ABSs, including Relator, and outside consultants regularly provide select physician practices with IOIs as well as targeted physician practices with IOIs practice management and infusion business advisory services and support on a wide range of topics enumerated in paragraph 166 of Relator's Second Amended Complaint ("SAC"). These free business advisory services along with the related presentations and programs Janssen utilized to provide the services are collectively referred to herein as "IOI Support."[1] Relator alleges that the IOI Support had substantial and broad value (beyond just Remicade and Simponi ARIA). The information and assertions from the *AWP Class Action* and the allegations from the *Heineman*

[1] Trying to make the IOI Support services at issue appear more innocuous and non-businesslike, Janssen in its briefing inaccurately refers to the valuable services at issue as "IOI education."

and *Greer* complaint do not allege the essential elements of the illegal remuneration and related AKS and FCA violations that Relator alleges, much less even suggest that Janssen provided the alleged illegal remuneration at the center of this action. Under the legal framework that the Court applied in assessing whether Relator's complaint states a plausible AKS violation, in order for services to constitute illegal remuneration, (a) the services must have had substantial independent value, (b) they must have been provided for free, (c) one of the purposes for providing the services must have been to induce prescriptions of the drug to Medicare beneficiaries, and (d) the company must have provided the services knowingly and willfully. *See* Oct. 21, 2020 Mem. & Order (ECF 75) at 12, 17-18, 23. Also, for the illegal remuneration to have resulted in an FCA violation, the recipients must have subsequently prescribed the drug and billed Medicare for reimbursement. *See id.* at 12. The vague and general references to "practice management programs," "business reviews," and "consultants" in the three earlier cases were not accompanied by any of the critical allegations or information that would have made the Government aware of the essential elements of the fraud Relator alleges:

- There was no allegation/report that the programs or business review related to the overall management and operation of the infusion business, beyond Remicade.
- There was no allegation/report that Centocor had employees and consultants regularly provide the programs and business reviews to select accounts after they had opened an IOI.
- There was no allegation/report that the programs, business reviews, and written materials were valuable to doctors and had substantial independent value beyond Remicade.
- There was no allegation/report that physicians did not have to pay for the programs and business reviews.
- There was no allegation/report that the programs and business reviews were not offered to all physicians, rather only select and targeted IOI customers.
- There was no allegation/report that would have created a plausible inference that Centocor knew that providing the programs and business reviews violated the law.

- There was no allegation/report that the doctors associated with physician practices that received the programs, business reviews, and written materials subsequently prescribed and infused Remicade and/or Simponi ARIA to Medicare beneficiaries and submitted false claims to Medicare to obtain reimbursement for the drugs and infusion procedures.

Apparently conceding that the essential elements of the fraud Relator alleges were not alleged or reported in the information, assertions, and allegations it assembled, Janssen now argues that the essential elements could have been inferred. But the collection of vague and innocuous purported disclosures does not provide a basis for such inferences. Also, because this motion is brought under Rule 12(c), all reasonable inferences must be drawn in favor of Relator. *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp.2d 39, 48-49 (D. Mass. 2011).

The information and assertions from the *AWP Class Action* and vague allegations from *Heineman* and *Greer* do not allege the essential elements of the AKS and FCA violations that Relator alleges or even suggest that Janssen provided the IOI Support at the center of this action.

C. Relator's Action Does Not Allege Substantially The Same Allegations As The Purported Disclosures From The Three Earlier Actions

Relator's allegations are not substantially the same as the purported disclosures from the *AWP Class Action*, the *Heineman* complaint, and the *Greer* complaint. Those cases did not report information or include allegations that put the Government on notice of the essential elements of the fraud Relator alleges. A comparison of the purported disclosures with the allegations in Relator's complaint, as well as the Court's October 21, 2020, decision on the motion to dismiss (ECF 75), makes clear that the fraud Relator alleges is substantially different.

II. RELATOR IS AN ORIGINAL SOURCE

The public disclosure theory Janssen has fabricated does not trigger the FCA's public disclosure bar (none of the three requirements are met). But, even if the assemblage of information, assertions, and allegations from the earlier cases did trigger the public disclosure

bar, Janssen's Hail Mary attempt would still fail because Relator is unquestionably an original source. As Relator's opening brief demonstrates, she is an original source because (1) she has "independent" knowledge of the fraud she alleges, (2) her knowledge and information materially add to any prior disclosures, and (3) she complied with the FCA's pre-suit disclosure requirements. Janssen does not dispute that Relator's knowledge of the fraud she alleges is independent or that she complied with the FCA's pre-suit disclosure requirements. It contends that Relator's additions to the purported disclosures are not material.

A relator's knowledge and information materially add to publicly disclosed allegations if it is "[o]f such a nature that knowledge of the item would affect a person's decision-making," or if it is "significant" or "essential." *Winkelman*, 827 F.3d at 211. "As the level of detail in public disclosures increases, the universe of potentially material additions shrinks." *Id.* Because Janssen's purported public disclosures provide none of the essential elements and practically zero detail about any fraud, an enormous amount of additional knowledge and information was required to adequately allege the fraud that Relator alleges and will be required to prove it. In short, the purported disclosures are of no value to this case.

In her opening brief, Relator sets forth the numerous essential and significant additions that she adds to the non-fraud, undetailed information and assertions from the *AWP Class Action* and the vague and bare allegations from *Heineman* and *Greer*. Janssen's meritless attempts to discredit Relator's essential additions should be rejected. Contrary to Janssen's contentions, this is not a case where an opportunist relator is merely adding a few details or color. Here, Relator is providing all the essential elements, details, and allegations, all of which are based upon her provision of the services that constitute the alleged illegal remuneration for nearly 13 years.

Most fundamentally, Relator provides the essential addition of specifically alleging that

Janssen's conduct violated the AKS and that those violations, in turn, caused doctors to submit false claims to Medicare in violation of the FCA. The Court scrutinized Relator's allegations under the heightened Rule 12(b)(6) and Rule 9(b) pleading standards in determining that they state plausible claims for violations of the AKS and FCA. *See* Oct. 28, 2020 Mem. & Order (ECF 75). On the other hand, no court would find that the alleged disclosures from the earlier actions collectively state a plausible claim that Centocor defrauded the Government. Janssen's assertion that the fraudulent nature of the conduct was obvious is false. The argument is belied not only by the undetailed, vague, and innocuous allegations and information itself but also by the motion to dismiss that Janssen filed three years ago.

In her opening brief, Relator also identifies ten other **material additions** that she provides to the purported disclosures that Janssen has stitched together:

1. The knowledge she gained from providing the IOI Support for 13 years, which has enabled her to plead the fraud with the requisite level of detail, particularity, and support needed to move beyond the pleading stage and to obtain the discovery needed to prove the allegations.
2. Specific and detailed information concerning the IOI Support that constitute the illegal remuneration.
3. Specific information about how Janssen provided the services to physician practices for free.
4. Specific and detailed information regarding the services' value, including their substantial value beyond Remicade and Simponi ARIA.
5. Specific and detailed information regarding how one of Janssen's main purposes in providing the alleged illegal remuneration was to induce doctors to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries.
6. Specific and detailed information, including quotes from internal documents, that created a plausible inference that Janssen knew that it was unlawful to provide the services to select physician practices for free in order to induce them to prescribe and infuse Remicade and Simponi ARIA.
7. Specific information linking Janssen's provision of the illegal remuneration to the subsequent submission of false claims to Medicare.

8. Specific and detailed information showing how the alleged illegal remuneration resulted in the submission of false claims to Medicare from October 2010 to the present, long after the alleged conduct in the earlier cases.

9. Relator's complaint alleges that starting in July 2013, Janssen provided the illegal remuneration to induce providers to prescribe Simponi ARIA in addition to Remicade.

10. Relator has obtained substantial additional information about the alleged fraud during discovery.

Janssen's attempts to degrade these material additions are meritless.

Material Addition 1 relates to Relator's voluntary sharing of the extensive knowledge, including numerous evidentiary documents, that she gained while providing, and arranging for outside consultants such as Xcenda to provide, the alleged illegal remuneration at Janssen's direction for nearly 13 years. This extensive first-hand knowledge enabled her to plead the fraud she alleges with the requisite level of detail and support needed to move beyond the pleading stage and to obtain the discovery needed to prove her allegations. Relator's voluntary sharing and use of her extensive knowledge is indisputably a material addition.

Material Addition 2 concerns the SAC's allegations that set forth in substantial detail the IOI Support that Janssen directed her, other ABSs, and outside consultants to provide and that constitute the alleged illegal remuneration in this action. Again, the Court summarized these allegations in the October 2020 Memorandum and Order denying Janssen's motion to dismiss (ECF 75). These are not mere details; they are the core allegations in this case.

Material Addition 3 is that the SAC reports the essential information that Janssen provided the IOI Support for free. This essential information was not reported or alleged in the earlier cases. Instead, Janssen argues that the Government would infer that Janssen is providing the IOI Support free of charge. There is no basis to conclude that the Government would assume that a drug company is providing, and having consultants provide, valuable business consultative services to select customers for free. As the SAC alleges, doctors pay significant fees to obtain

these services directly from consultants. *See* SAC at ¶¶132-134, 179.

Material Addition 4 is that the SAC reports the essential information that the IOI Support had substantial independent value beyond Remicade and Simponi ARIA. Janssen points to no allegation or information from the earlier cases regarding the value of the services at issue, let alone information that shows the services had substantial independent value. In a full reversal from the argument it has been asserting throughout this action, including in its original motion to dismiss, that the IOI Support had no value beyond Janssen's drugs, Janssen now appears to argue that it is obvious that the IOI Support has substantial independent value beyond Remicade and Simponi ARIA. Janssen's new position was never previously disclosed. Relator's allegations regarding the substantial independent value of the IOI Support are an essential addition.

Material Addition 5 relates to Relator's allegations that one of Janssen's main purposes in providing the alleged illegal remuneration was to induce doctors to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries. These allegations are likewise essential additions; the earlier cases do not make such allegations or provide this information.

Material Addition 6 concerns the specific and detailed information that created a plausible inference that Janssen knew that it was unlawful to provide the services to select physician practices for free in order to induce them to prescribe and infuse Remicade and Simponi ARIA. Janssen states that its assembly of snippets from the earlier cases revealed that Janssen acted willfully in providing the illegal remuneration alleged here. This is incorrect. The vague and conclusory scienter allegations from the *Heineman* and *Greer* complaints that Janssen relegates to a footnote in its reply, *see* Reply at 14, n.15, cannot give rise to a plausible inference that Centocor acted knowingly and willfully in providing the IOI Support. And Centocor asserted that it believed its provision of the programs and written materials referenced in the *AWP Class*

Action was lawful, not unlawful. *See* Relator's Ex. 2 - Alleged Disclosures E, F, J.

Material Addition 7 relates to the specific information that the SAC alleges linking Janssen's provision of the illegal remuneration to the subsequent submission of false claims to Medicare, which was closely assessed by the Court and determined to satisfy the heightened requirements for alleging fraud. *See* Oct. 21, 2020 Mem. and Order (ECF 75) at 26-33. Janssen does not–and cannot–argue that these essential allegations are not a material addition.

Material Addition 8 is that Relator's allegations relate to a later time period that began well after the conduct reported in the three earlier cases. Courts sensibly recognize that past allegations of fraud do not forever immunize that scheme from a qui tam action. *See U.S. ex rel. Booker v. Pfizer, Inc*., 9 F. Supp.3d 34, 45 (D. Mass. 2014); *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp.3d 332, 353 (S.D.N.Y. 2014); *U.S. ex rel. Fernandez v. Freedom Health Inc*., No.18-01059, 2021 WL 2954415, at *4-5 (M.D. Fla. May 26, 2021). The practices and conduct reported in the *AWP Class Action* and the *Heineman* and *Greer* complaints predated March 2007, and none of the information or allegations disclosed in those cases gave any clear indication that Centocor planned to continue engaging in the referenced conduct in perpetuity. *C.f. Winkelman*, 827 F.3d at 221 (finding public disclosures made it clear that defendant intended to continue engaging in the disclosed fraud). Relator's allegations that Janssen provided the IOI Support in violation of the AKS and FCA from October 2010 through the present, long after the alleged conduct from the earlier cases, is a material addition.

Material Addition 9 is that the SAC alleges that, starting in July 2013, Janssen provided the IOI Support to induce providers to prescribe Simponi ARIA in addition to Remicade. This addition is material because, in addition to reporting that the alleged kickback scheme caused providers to submit false claims to Medicare related to a second drug, it shows that the IOI

Support's advice and value extended to multiple infusible drugs, not just one.

Material Addition 10 concerns the substantial additional information supporting and enhancing Relator's allegations that has been obtained since the SAC was filed in February 2020. Janssen falsely asserts that information obtained in discovery is not a material addition. This information and evidence were only obtained as result of Relator's allegations and efforts and further demonstrate the materiality of the additions stated above. This material addition cannot be ignored. Moreover, the discovery obtained further highlights the substantive differences between the IOI Support at issue here and the services and conduct that were referenced in the earlier actions when the fraud Relator alleges was only in its infancy.

Relator's knowledge, information, and allegations overwhelmingly materially add to any prior disclosures. If Julie Long does not qualify as an original source, no one would qualify.

III. CONCLUSION

Because the information, assertions, and allegations from the *AWP Class Action*, *Heineman*, and *Greer* do not constitute public disclosures under the FCA, and, even if they did, Relator is the original source of her allegations, Janssen's motion should be denied.

Dated: April 28, 2023

Respectfully submitted,

/s/ Theodore J. Leopold

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CERTIFICATE OF SERVICE

I hereby certify on this 28th day of April, 2023, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

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